

EXHIBIT A

IN THE UNITED STATES  
PATENT AND TRADE MARK OFFICE

DECLARATION OF KRISTEN LAVOIE  
RE PATENT APPLICATION NO. 09/364,343

I, Kristen Lavoie, of 114 Whitwell Street, Quincy, MA 02169,  
do declare and say as follows:

1. My professional background is as follows: I am a Registered Nurse, and a certified wound care specialist (ET/Ostomy), and I am CWOCN certified. I am a graduate of the University of Lowell, in Lowell, MA, and completed the Lucy Wick ~~Enterostomal~~ Enterostoma<sup>KL</sup> Therapy Course in open wounds. I have been a registered nurse for 9 years.

As such, I am deeply familiar with means of treating wounds in patients, including wound irrigation delivery systems using separate sealed sterilized bottles of saline solution, sterile bowls and sterile syringes, which are presently in use.

2. I have reviewed U.S. patent application No. 09/364,343 entitled "Wound Irrigation and Debriding System", invented by Jacqueline R. Doyle and Kenneth F. Short, and I am familiar with this invention.
3. I have reviewed the U.S. Patent Office Action dated 02/07/02 and the cited references: U.S. Patents No. 4,752,288 of Hussey, entitled "Disposable Enema Unit"; No. 2,135,052 of Rose, entitled "Nasal Douche"; and No. 4,894,054 of Reddick, entitled "Douche Apparatus"; and No. 6,066,325 of Wallace et al, entitled "Fragmented Polymeric Composition and Methods for their use".
4. In my opinion, the wound irrigation and debriding system of Jacqueline Doyle and Kenneth Short is a significant and surprising advance in this field of medicine as compared with the present state of the art. The accepted system of using independently

packaged items which are then reassembled and in which the solution is drawn-into a syringe and injected into the patient is time-consuming, especially in emergencies, subject to possible contamination, and requires discard into a Sharps Hazard Container.

5. The enema unit of Hussey is used in an entirely different medical procedure than the wound irrigation and debriding system of the inventors. The enema must be inserted into the rectum of the patient; the wound irrigation and debriding system of the inventors in the pending application is non-invasive, and is not capable of acting as an enema. Nor, in my opinion, is the enema of Hussey capable of performing the wound irrigation and debriding claimed by the present inventors.

Structurally, Hussey's enema and applicants' wound irrigation system are substantially different. Because Hussey claims an enema, it requires a rectal tip and lubricant for insertion into the rectum. It also requires a heat-shrunk protective sleeve fixed to a ball and the rectal tip.

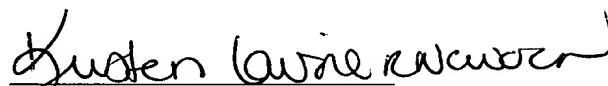
6. As a practicing registered nurse knowledgeable in the field of wound irrigation, enemas and douches, it would not be obvious to me to combine the enema of Hussey with any of the prior art patents cited by the examiner as listed in paragraph 3 of this Declaration in order to produce applicants' invention.
7. If Hussey, as I conclude, is designed as an enema, and is not meant or capable to be a wound irrigation and debriding system as taught by applicants, the filter used by Reddick's douche apparatus would not change the nature of Hussey's invention and would certainly not make applicants' invention obvious to me or anyone else skilled in the art of this invention.
8. My conclusions are the same in this regard as concerns the angled nozzle used by Rose's nasal douche, and the hydrogels of Wallace, et al.
9. I do not conclude that applicants' invention lies in the use of filters, types of nozzles or the ability to dispense fluids.

10. My understanding of applicants' wound irrigation and debriding system is that, for the first time known to me, this invention provides a one-piece system (as opposed to present independently packaged units), which does not require a syringe, nor Sharps Hazards disposal procedures, is non-invasive, and which is more efficient, quicker, safer, and less expensive than presently available today.

Witness my hand and seal this 11<sup>th</sup> day of December 2002.

Kristen Lavoie

Witness: 

  
Signature